OLYMPUS

Your Vision, Our Future

OLYMPUS KEYMED

KeyMed House, Stock Road, Southend-on-Sea, Essex, SS2 5QH, UK

Telephone: +44 (0)1702 616333 Facsimile: +44 (0)1702 465677

K 100899-

Pg 1 of 3

510 (K) SUMMARY
OLYMPUS ENDOSCOPIC FLUSHING PUMP OFP-2

Contact Name:

Company: KeyMed (Medical & Industrial Equipment) Ltd

Address: KeyMed House
Stock Road
Southend-on-Sea
Essex SS2 5QH
UK

SEP 13 2010

Telephone: +44 (0)1702 616 333

Fax: +44 (0)1702 465 677

E-mail:

Owner/Operator #: 8020728

Establishment Registration #: 9611174

Date of Preparation: 22 March 2010

Name of Device: Olympus Endoscopic Flushing Pump (OFP-2)

Common Name: Endoscopic Flushing or Lavage Pump

Classification Name: Pump, Air, Non-Manual, For Endoscope

Product Code: FEQ (21 CFR 876.1500)
(as per classification of predicate device)

Basis of submission: This submission claims substantial equivalence to the following legally marketed devices:

- Olympus Endoscopic Flushing Pump, OFP-1 (K000948)
- Olympus AFU-100 (K073207)
- Olympus UWS1 Water Supply Unit (K951994)

OLYMPUS

Your Vision, Our Future

K100899

DEVICE DESCRIPTION

The Olympus Endoscopic Flushing Pump (OFP-2) is a motorised pump designed to transfer water from a bottle, via a tube, to an endoscope.

The OFP-2 uses a peristaltic pump head to move the water through the tube. The speed of rotation of the pump head is adjustable by the user, over nine steps, using flow control buttons on the front of the pump. The flow control buttons are connected to a digital controller that governs speed of rotation of the pump head. Nine LEDs on the front of the pump indicate the speed setting that has been selected.

The pump is operated by a footswitch or a button on the endoscope. It has an on/off button and a standby button.

The OFP includes a water container supplied non-sterile to be processed before use. Two water tubes of different lengths and an instrument channel adapter are supplied sterile. The Instrument Channel Adapter (MAJ-1606) and Instrument Channel Water Tube (MAJ-1607) are supplied sterile for single use only, to pump water through the instrument channel of the endoscope. The Auxilliary Channel Water Tube (MAJ-1608) is supplied sterile for single day only use.

INDICATIONS FOR USE

The OFP-2 and accessories are intended for use in medical facilities under the direction of a trained physician.

The OFP-2 is intended for use:

- During endoscopic procedures to wash blood, feces and other organic matter from the site being visualised, diagnosed or treated.
- To aid in filling areas of the gastrointestinal tract with water in order to aid in examinations performed with trans-endoscopic ultrasound probes

SUMMARY OF TESTING

Risk Management of the OFP-2 and its tubing was performed to ISO 14971 and included a device hazard analysis.

Biocompatibility of the Water Container and tubing has been established by subjecting the container, a tube and the Instrument Channel Adapter to the following tests:

- L929 MEM elution test to ISO 10993-5
- Intracutaneous Injection Test to ISO 10993-10
- Kligman Maximization Test to ISO 10993-10

Electrical safety testing of the OFP-2 and its accessories was performed to:

- IEC 60601-1:1988
- EN 60601-1:1990
- UL 60601-1:2003
- CAN/CSA-C22.2 No. 601.1-M90

Additional testing was performed to:

- IEC 60601-1-1
- IEC 60601-2-18

The effectiveness of steam sterilization on the water container was validated, as was the robustness of the water container when subjected to steam sterilization over the expected useful life of the container.

The performance of the OFP-2 and its accessories was verified and validated.

EQUIVALENCE TO PREDICATE DEVICES

Substantial equivalence to the Olympus Flushing Pump (OFP-1)(K000948)

The proposed device, the OFP-2, is substantially equivalent to the OFP-1 in the following ways:

- Both devices share the same intended use
- Both devices utilize the same method of operation
- Both devices utilize the same method of connection – a Luer compatible fitting – to connect the water supply tube to the Auxiliary Channel of the endoscope

Substantial equivalence to the Olympus AFU-100 peristaltic pump unit (K073207)

The proposed device, the OFP-2, is substantially equivalent to the Olympus AFU-100 in the following ways:

- Both devices share the same intended use
- Both devices share the same method of operation. The OFP-2 is supplied with a foot switch which is optional on the AFU-100.
- Both devices utilize the same method of connection – a Luer compatible fitting – to connect the water supply tube to the endoscope. The OFP-2 uses an additional adapter – MAJ1606, included in this application – to connect to the Instrument Channel of some endoscopes.

Substantial equivalence to the Olympus UWS-1 water supply unit (K951994)

The proposed device, the OFP-2, is substantially equivalent to the Olympus UWS-1 water supply unit in the following ways:

- Both devices share the same intended use
- Both devices share a similar method of operation. The circuit formed by the water container, tube and endoscope is functionally equivalent. The OFP-2 uses a peristaltic pump to move the fluid along the tube while the UWS-1 uses an electromagnetic pump.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

KeyMed (Medical & Industrial Equipment) Ltd
% Mr. Ron Warren
Principal Consultant, Regulatory Services
Medical Device Consultants, Inc.
11440 West Bernardo Drive, Suite 300
SAN DIEGO CA 92127

SEP 13 2010

Re: K100899
Trade/Device Name: Olympus Endoscopic Flushing Pump (OPF-2)
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FEQ
Dated: March 29, 2010
Received: June 16, 2010

Dear Mr. Warren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

SEP 13 2010

510(k) Number (if known): K100899

Device Name: OLYMPUS ENDOSCOPIC FLUSHING PUMP (OPF-2)

And accessories : MAJ – 1603: Water Container (2L) 3 pack

MAJ – 1606: Instrument Channel Adapter

MAJ – 1607: Instrument Water Tube

MAJ – 1608: Auxiliary Channel Water Tube

Indications For Use:

The OLYMPUS FLUSHING PUMP (OFP-2) and its accessories are intended for use during endoscopic procedures to wash blood, feces and other organic matter from the gastric and colonic mucosa site being visualized, diagnosed and/or treated and to aid in the filling areas of the gastrointestinal tract with water in order to aid in examinations preformed with trans-endoscopic ultrasound probes.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K100899